No. 17-1229

IN THE

# Supreme Court of the United States

HELSINN HEALTHCARE S.A.,

*Petitioner,*

*v.*

TEVA PHARMACEUTICALS USA, INC. and
TEVA PHARMACEUTICAL INDUSTRIES, LTD.

*Respondents.*

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

## BRIEF OF *AMICUS CURIAE* US INVENTOR, INC. IN SUPPORT OF PETITIONER HELSINN HEALTHCARE S.A.'S PETITION FOR A WRIT OF CERTIORARI

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**Cases**

*August Bentkamp v. United States*,
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*Barnhart v. Thomas*,
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*Campbell v. United States*,
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*Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.*,
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*Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.*,
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*Jarecki v. G.D. Searle & Co.*,
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*Jimenez v. Quarterman*,
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*Lockhart v. United States*,
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*Market Company v. Hoffman*,
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*United States v. Begaye*,
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*X-Acto Crescent Prods. Co., Inc. v. United States*,
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*Yates v. United States*,
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**Statutes & Rules**

Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 254 (2011) ("AIA"), 35 U.S.C. § 102 ..... *passim*

17 C.F.R. § 240.12b-2 ..... 8

**Congressional Records**

154 Cong. Rec. S9992 (daily ed. Sept. 27, 2008) ..... 14

157 Cong. Rec. H4429 (daily ed. June 22, 2011) ..... 14

157 Cong. Rec. S1368 (daily ed. Mar. 8, 2011) ..... 13

157 Cong. Rec. S5431 (daily ed. Sept. 8, 2011) ..... 14

H.R. Rep. No. 112–98, 112th Cong., 1st Sess. (June 1, 2011) ..... 13

S. Rep. No. 111-18, 111th Cong., 1st Sess. (May 12, 2009) ..... 13

**Other Authorities**

Armitage, R.A., *Understanding the America Invents Act and Its Implications for Patenting*, 40 AIPLA Q. J. 1 (2012) ..... 3

Cited Authorities

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Brief for The Naples Roundtable, Inc. as Amicus Curiae Supporting Plaintiffs-Appellees, *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.*, 855 F.3d 1356 (Fed. Cir. 2017) (No. 2016-1284, 2016-1287) .....4

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M. Meng, "With high-performance cells, China takes aim at high-end solar market," *available at* https://www.reuters.com/article/us-china-solar-cost-analysis/with-high-performance-cells-china-takes-aim-at-high-end-solar-market-idUSKCN1BP0X6 .....6

P. Morinville, "Crisis in American Innovation," US Inventor, *available at* http://www.usinventor.org/wp-content/uploads/2017/08/USI-Crisis-in-American-Innovation-Full-Version.pdf. .....5

Cited Authorities

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J. Pekkanen, "China Leads The Quantum Race While The West Plays Catch Up," *available at* https://www.forbes.com/sites/saadiampekkanen/2016/09/30/china-leads-the-quantum-race-while-the-west-plays-catchup/#b14212592856 .....6

Small Business Administration, Office of Advocacy: The Voice of Small Business in Government (updated Jan. 2011), *available at* https://www.sba.gov/sites/default/files/sbfaq.pdf .....7

Tufts Center for the Study of Drug Development (CSDD), "Tufts CSDD Assessment of Cost to Develop and Win Marketing Approval for a New Drug Now Published," *available at* http://csdd.tufts.edu/news/complete_story/tufts_csdd_rd_cost_study_now_published .....8

J. Vincent, "China overtakes US in AI startup funding with a focus on facial recognition and chips," *available at* https://www.theverge.com/2018/2/22/17039696/china-us-ai-funding-startup-comparison.....5

WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY (2002). 10

WIPO, "Global Patent Applications Rose to 2.9 Million in 2015 on Strong Growth From China; Demand Also Increased for Other Intellectual Property Rights," *available at* http://www.wipo.int/pressroom/en/articles/2016/article_0017.html .....6

## I. Interests of Amicus Curiae US Inventor, Inc.[1]

US Inventor, Inc. ("US Inventor") is a non-profit association of inventors devoted to protecting the intellectual property of individuals and small companies. It represents its 13,000 inventor and business members by promoting strong intellectual property rights and a predictable U.S. patent system through education, advocacy, and reform.

US Inventor was founded to support the innovation efforts of the "little guy" inventors, seeking to ensure that strong patent rights are available to support their efforts to develop their inventions, bring those inventions to a point where they can be commercialized, create jobs and industries, and promote continued innovation. Its members consist of individual inventors and small- to medium-sized enterprises that depend heavily on the value created by meaningful patent rights. Their broad experience with the patent system, new technologies, and creating companies, gives them a unique perspective on the important issues presented in Helsinn Healthcare, S.A.'s petition for a writ of certiorari.

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1. Pursuant to Supreme Court Rule 37, all parties received notice of amicus curiae US Inventor's intent to file this brief 10 days before its due date. All parties to this matter have filed letters granting blanket consent to amicus curiae briefs. Amicus US Inventor certifies that no counsel for a party authored this brief in whole or in part, and no party or counsel for a party made a monetary contribution intended to fund preparing or submitting this brief. No person or entity, other than amicus, its members, or its counsel, contributed money intended to fund preparing or submitting this brief.

## II. Summary of the Argument

This Court should grant certiorari because the Federal Circuit has decided an important question of law in a way that conflicts with the plain language of § 102(a)(1) of the America Invents Act ("AIA"), and is otherwise unsupported. The Federal Circuit's *Helsinn* opinion conflicts with the AIA's legislative history, conflicts with the USPTO's analysis and interpretation of the statute, and conflicts with prevalent canons of statutory construction. If allowed to stand, the *Helsinn* opinion will have a severe and disproportionate impact on the small U.S. inventor—the life and blood of our economy—whose interests our patent law system is supposed to foster and protect. It is critically important that this Court grant Helsinn's petition for a writ of certiorari.

## III. Argument

### A. The Federal Circuit's Interpretation of Section 102(a) Is Contrary to the Purpose of the AIA and Destroys Harmony with Foreign Law.

An explicit objective of the Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 254 (2011) ("AIA"), was to "establish a more efficient and streamlined patent system that will improve patent quality and limit unnecessary and counterproductive litigation costs." H.R. Rep. No. 112–98, 112th Cong., 1st Sess. (June 1, 2011) ("AIA Committee Report") at 40. A profound change effected by the AIA was the conversion of the American patent system from a "first-to-invent" to a "first-inventor-to-file" system, thereby taking a major step towards harmonizing the American patent system with the systems of other leading

industrialized countries around the world. *Id.* This change stemmed from Congress's recognition that it is "common for inventors and companies to file for protection in several countries at the same time." *Id.* at 41. An important goal of harmonization was to eliminate the need for patent applicants to comply with multiple incompatible patent systems.

As part of that harmonization, Congress redefined the scope of invalidating prior art under § 102 as follows:

> A person shall be entitled to a patent unless—
> (1) the claimed invention was patented, described in a printed publication, *or* in public use, on sale, *or otherwise available to the public* before the effective filing date of the claimed invention ....

AIA 35 U.S.C. § 102(a)(1) (emphasis added).[2]

A primary purpose of the "on-sale" bar is to "exclude from consideration for patent protection knowledge that is *already available to the public*" on the grounds that "the creation of a monopoly in such information would not only serve no socially useful purpose, but would in fact injure the public by *removing* existing knowledge from public use." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 148 (1989) (emphasis added). By enacting the AIA and making explicit the requirement that prior

2. The redefinition of the scope of prior art is only one of the significant changes wrought by the AIA. For a comprehensive list of those changes, see R.A. Armitage, *Understanding the America Invents Act and Its Implications for Patenting*, 40 AIPLA Q. J. 1, 10-14 (2012).

art make the claimed invention available to the public to qualify as potentially invalidating, Congress affirmed that longstanding purpose.

Construing AIA § 102(a)(1) as excluding as prior art sales that have not made the invention "available to the public" also comports with the AIA's overarching goal of "harmonizing our system for granting patents with the best parts of other major patent systems throughout the industrialized world." AIA Committee Report at 39. No other major industrialized nation defines invaliding prior art as encompassing secret sales. *See, e.g.*, Brief for The Naples Roundtable, Inc. as Amicus Curiae Supporting Plaintiffs-Appellees at 6-13, *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.*, 855 F.3d 1356 (Fed. Cir. 2017) (No. 2016-1284, 2016-1287). Interpreting the on-sale bar to encompass secret sales would undermine Congress's goal of ensuring that what counts as prior art under American law is consistent with prior art recognized by other nations.

Before the AIA was enacted, an invention that was "in public use" or "on sale" precluded the grant of a patent only if such public use or sale occurred "in this country." Pre-AIA 35 U.S.C. § 102(b). Prior art now encompasses "all art that *publicly exists* prior to the filing date" regardless of geographical location. AIA Committee Report at 42 (emphasis added). This geographical expansion is interconnected with the limitation of prior art to the categories of *publicly available* materials listed in § 102(a)(1), including those "in public use" or "on sale." Both the geographical expansion and the restriction of prior art to publicly available materials harmonize U.S. law with foreign law regarding the bases for invalidity. The Federal Circuit opinion, which did not address the AIA Committee Report for the enacted version of the AIA,

utterly defeats a major purpose of Congress in enacting § 102(a)(1), and renders the United States, once again, out of step with the rest of the world.

### B. The "Little Guy" Stands to Bear a Disproportionate and the Most Destructive Brunt of this "On Sale" Bar Storm.

The small inventor is the true representative of the culture of innovation and ingenuity that Article I, Section 8, Clause 8 of the Constitution was meant to promote and foster. The Federal Circuit's *Helsinn* opinion effects a direct hit on this country's grassroots inventive ethos by disincentivizing the risk-taking and experimentation that are inherent in the inventive process, and creating uncertainty with respect to development and commercialization of inventions.[3]

The *Helsinn* opinion is especially problematic because it comes at a time when the United States is facing a true crisis in innovation. Countries that were once net importers of advances in technology are now eclipsing the United States with respect to advances in the industries of the future. For example, in 2017, China accounted for 48% of the world's total artificial intelligence startup funding, while the United States accounted for only 38% of such funding.[4] China is either already leading or is

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3. *See generally* P. Morinville, "Crisis in American Innovation," US Inventor, *available at* http://www.usinventor.org/wp-content/uploads/2017/08/USI-Crisis-in-American-Innovation-Full-Version.pdf.

4. *See* J. Vincent, "China overtakes US in AI startup funding with a focus on facial recognition and chips," at 1, *available at* https://www.theverge.com/2018/2/22/17039696/china-us-ai-funding-startup-comparison.

becoming the world leader in quantum computing, solar cells, and other technologies that provide the foundation for several important industries, including advanced energy production and globalized currencies.[5] These changes are reflected in the significant difference in the number of patent applications between the two countries: by 2015 nearly twice as many patent applications were filed in China (1,101,864) as were filed in the United States (589,410).[6] In the first quarter of 2017, the number of angel and seed stage funding rounds in the United States dropped 62 percent.[7] Entrepreneurs have found it harder and harder to raise money through venture capital.[8]

If allowed to stand, the Federal Circuit's opinion in *Helsinn* will cause significant irreparable harm to small inventors, who are critical to the innovation ecosystem. As

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5. *See* J. Pekkanen, "China Leads The Quantum Race While The West Plays Catch Up," at 2, *available at* https://www.forbes.com/sites/saadiampekkanen/2016/09/30/china-leads-the-quantum-race-while-the-west-plays-catchup/#b14212592856; M. Meng, "With high-performance cells, China takes aim at high-end solar market," *available at* https://www.reuters.com/article/us-china-solar-cost-analysis/with-high-performance-cells-china-takes-aim-at-high-end-solar-market-idUSKCN1BP0X6.

6. WIPO, "Global Patent Applications Rose to 2.9 Million in 2015 on Strong Growth From China; Demand Also Increased for Other Intellectual Property Rights," at 1, *available at* http://www.wipo.int/pressroom/en/articles/2016/article_0017.html.

7. *See* M. Kendall, "Silicon Valley investing slump continues, fewer startups get funded," at 4, *available at* https://www.siliconvalley.com/2017/04/04/silicon-valley-investing-slump-continues-fewer-startups-get-funded/.

8. *Id.*

of about a decade ago, they hired 43 percent of America's high tech workers (*e.g.*, scientists, engineers, computer programmers), produced 16.5 times more patents per employee than large patenting firms, generated 65 percent of net new jobs over the previous 17 years, and made up 97.5 percent of all identified U.S. exporters.[9]

Small inventors often lack the resources or manufacturing ability to develop their inventions themselves. They rely on development arrangements and seed funding to pay for the significant costs of patent prosecution and of engaging in further experimentation, discovery, and invention development. They need to be able to rely on their intellectual property rights as a basis for attracting businesses that may be interested in those innovations, and in partnering, collaborating, or investing in them. Confidential inclusion of patent rights as part of a transaction is an essential step in enabling a small inventor to bring an invention from its conception to the point where it becomes a contribution to society. Trial and error are inherent in the innovation process, and significant work may only yield a small amount of patentable, and commercially viable matter. If inventors cannot disclose their inventions under confidentiality agreements as part of their business development transactions without fear that they are thereby placing the patentability of those inventions in jeopardy, future innovation, collaboration, and development will be severely chilled.

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9. Small Business Administration, Office of Advocacy: The Voice of Small Business in Government (updated Jan. 2011), *available at* https://www.sba.gov/sites/default/files/sbfaq.pdf.

This is especially true when inventions are being developed by smaller companies, where an agreement with another company to fund or share the costs of development may rise to the level of materiality, and thus obligate such companies under federal securities laws to disclose the agreement in their public filings (as occurred in *Helsinn*). *See* 17 C.F.R. § 240.12b-2. (SEC defining "material" as those matters to which there is a substantial likelihood that a reasonable investor would attach importance in determining whether to buy or sell the securities registered). This means that the materiality threshold for including information in the SEC filings of a million-dollar company is far lower than it is for a billion-dollar company—small businesses have to disclose much smaller transactions to comply with the SEC's materiality requirement than large businesses do. Small businesses also will face difficulty in attracting and co-developing or acquiring rights to inventive ideas for development and public benefit.

In the pharmaceutical industry, drug development typically requires many years and billions of dollars.[10] In order for smaller companies to participate in the drug development process, they necessarily must partner with larger companies or venture capital funding sources. If a conveyance of rights to the invention is included as part of the collaboration agreement such that it qualifies as a "sale," *Helsinn* renders that agreement invalidating prior art, even if the invention itself is not disclosed to, or otherwise put in the hands of, the public.

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10. *See* Tufts Center for the Study of Drug Development (CSDD), "Tufts CSDD Assessment of Cost to Develop and Win Marketing Approval for a New Drug Now Published," *available at* http://csdd.tufts.edu/news/complete_story/tufts_csdd_rd_cost_study_now_published.

The Federal Circuit also injected uncertainty and unpredictability into a judicially created "existence of sale" bar by making statements such as, "We do not find that distribution agreements will always be invalidating under § 102(b). We simply find that this particular Supply and Purchase Agreement is." *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.*, 855 F.3d 1356, 1371 (Fed. Cir. 2017). This particular Supply and Purchase Agreement, however, was redacted, and did not disclose the claimed invention. *Helsinn*, 855 F.3d at 1361-62.

The Federal Circuit has created a Hobson's choice for the small inventor, both alternatives of which are detrimental to innovation and against the public interest: collaborate and develop your invention but give up your patent rights by doing so (thus killing the invention, and keeping the public from benefiting from it in the process), or patent it but do not enter into the agreements necessary to develop it, and thus leave it and the patent sitting on a shelf (thus killing the invention, and keeping the public from benefiting from it in the process).

Small inventors face numerous challenges and obstacles these days, and a dependable and clear patent protection framework is an essential foundation for them to be able to survive and thrive. They need this Court to address and reverse the *Helsinn* opinion, before it and its progeny cause irreparable damage.

### C. The Federal Circuit's Opinion Is Contrary to the Plain Language of the Statute.

"As with any question of statutory interpretation, [the Court's] analysis begins with the plain language of the

statute." *Jimenez v. Quarterman*, 555 U.S. 113, 118 (2009) (citation omitted). It is well settled that when interpreting a statute, one must begin with "the assumption that the ordinary meaning of the language chosen by Congress accurately expresses the legislative purpose." *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 101 (2011) (internal quotation marks, modification, and citation omitted).

The ordinary meaning of § 102(a)(1) of the AIA requires that a sale of a claimed invention make the claimed invention "available to the public," in order for the sale to qualify as invalidating prior art. "Patented," "described in a printed publication," "public use," and "on sale" are all specific circumstances in which the claimed invention can be made available to the public. The catchall category "or otherwise available to the public," coming as it does at the end of the list of prior art categories, then references other ways in which the invention can be made "available to the public," and confirms that the terms preceding it—including the term "on sale"—also involve making the invention "available to the public."

Webster's Third New International Dictionary defines "otherwise" as "in a different way or another manner." WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 1598 (2002). In order for a claimed invention to become "available to the public" in a "different way or manner," there must be a referenced "way or manner" in which the invention is "available to the public."

In plain English, "or otherwise available to the public" means "or *in other ways* available to the public." The use of the "or otherwise" clause thus linguistically indicates that the "on sale" activity must make the claimed

invention "available to the public." This Court made a similar observation in *United States v. Standard Brewery, Inc.*, 251 U.S. 210, 217-18 (1920), disagreeing with the government's position that a statute prohibiting products for making "beer, wine, or other intoxicating malt or vinous liquor for beverage purposes" encompassed "beer and wine whether intoxicating or not," and concluding that the provision aimed "only at intoxicating beverages."

Any other interpretation of the statutory text would ignore or render superfluous the term "or otherwise," which would, in turn, violate "one of the most basic interpretive canons, that a statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant." *Corley v. United States*, 556 U.S. 303, 314 (2009) (internal quotation marks, modification, and citation omitted). Indeed, this Court has long recognized that it is "not at liberty to construe any statute so as to deny effect to any part of its language." *Market Company v. Hoffman*, 101 U.S. 112, 115-16 (1879). The "or otherwise" language is in the statute for a reason. The *Helsinn* opinion effectively erases the "or otherwise" language from the statute.

Interpreting "on sale" to encompass secret sales would also be contrary to the most natural reading of the text. There is no dispute that the first three categories of prior art listed in § 102(a)(1)—inventions that are "patented," "described in printed publications," or "in public use"—are necessarily public. "In public use," and "on sale" both follow the ", or" that Congress added after "printed publication"—which deliberately set off the language: "or in public use, on sale or otherwise available to the public." Given that the penultimate category of prior art—

inventions that are "on sale"—is followed by the catchall category, "or otherwise available to the public," it stands to reason that, like the three preceding categories of prior art, and like the subsequent catchall category, sales also have to make the invention available to the public in order to qualify as potentially invalidating prior art. All five categories share the commonality of being "available to the public."

If Congress had wanted to exempt sales from the requirement that they be public to qualify as prior art, it could easily have drafted the statute so that it says so. For example, Congress could have placed the "otherwise available to the public" clause before "on sale" in the series, so that the section read: "[a] person shall be entitled to a patent unless—(1) the claimed invention was patented, described in a printed publication, in public use, or otherwise available to the public, or on sale, before the effective filing date of the claimed invention . . . ." Congress did not do so. The most natural and only reasonable interpretation of the language Congress actually chose is that the "claimed invention" that is "on sale" must be "available to the public" in order for the "sale" to be invalidating prior art. The term "otherwise" and the comma before the phrase "or otherwise available to the public" do not leave room for any other reasonable interpretation.

### D. The Opinion Is Contrary to the Legislative History of § 102(a).

The House Committee Report accompanying the AIA could hardly be clearer that Congress intended to redefine the scope of invalidating prior art to exclude

art that was not publicly available: "[p]rior art will be measured from the filing date of the application and will typically include all art that *publicly exists* prior to the filing date, other than disclosures by the inventor within 1 year of filing." AIA Committee Report at 42 (emphasis added). The Report explains: "Thus, in section 102 the 'in this country' limitation as applied to 'public use' and 'on sale' is removed, and the phrase 'available to the public' is added to clarify the broad scope of relevant prior art, as well as to *emphasize the fact that it must be publicly available.*" *Id.* at 42-43 (emphasis added); *see also* S. Rep. No. 111-18, 111th Cong., 1st Sess. at 6 (May 12, 2009).

The theme of public availability was reiterated by Senator Kyl on March 8, 2011, when he explained that Congress chose the word "otherwise" to "make[] clear that the preceding clauses describe things that are of the same quality or nature as the final clause—that is, although different categories of prior art are listed, all of them are limited to that which makes the invention 'available to the public.'" 157 Cong. Rec. S1368, S1370 (daily ed. Mar. 8, 2011) (statement of Sen. Kyl) (cited in final Committee Report, H.R. Rep. No. 112-98, at 43 n.20 (June 1, 2011)). In a hearing on the final bill on September 8, 2011, Senator Kyl again observed:

> As Chairman Smith most recently explained in his June 22 remarks, "contrary to current precedent, in order to trigger the bar in new 102(a) in our legislation, an action must make the patented subject matter 'available to the public' before the effective filing date." . . . When the committee included the words "or otherwise available to the public" in section 102(a), the

> word "otherwise" made clear that the preceding items are things that are of the same quality or nature. As a result, the preceding events and things are limited to those that make the invention "available to the public."

157 Cong. Rec. S5431 (daily ed. September 8, 2011) (statement of Sen. Kyl) (quoting 157 Cong. Rec. H4429 (daily ed. June 22, 2011) (statement of Rep. Smith)).

A few years earlier, Senator Kyl explained that the purpose of "eliminating confidential sales and other secret activities as grounds for invalidity and imposing a general standard of public availability" was to "make the patent system simpler and more transparent," which change, in turn, will "provide greater certainty and predictability—it should also substantially reduce the need for discovery in patent litigation, since defendants will no longer need to uncover evidence of private sales or offers for sale or other nonpublic information in order to determine whether the patent is valid." 154 Cong. Rec. S9992 (daily ed. Sept. 27, 2008) (statement of Sen. Kyl).

The Federal Circuit's suggestion that Congress either was not aware of how it was revising the scope of invalidating prior art, or was not aware of the consequences its changes would have, *Helsinn*, 855 F.3d at 1371, is untenable. Congress intended to revise the scope of invalidating prior art so that it did not encompass secret sales; the language it chose "accurately expresses [its] legislative purpose." *Microsoft*, 564 U.S. at 101.

### E. The Opinion Is Contrary to the USPTO Interpretation and Guidelines.

Based on its review of the statutory text and the legislative history, the U.S. Patent Office concluded that the AIA requires that sales under § 102(a)(1) must be publicly available: "[t]he phrase 'on sale' in AIA 35 U.S.C. 102(a)(1) is treated as having the same meaning as 'on sale' in pre-AIA 35 U.S.C. 102(b), ***except that the sale must make the invention available to the public.***" Examination Guidelines for Implementing the First Inventor to File Provisions of the Leahy-Smith America Invents Act, 78 Fed. Reg. 11059, 11075 (Feb. 14, 2013) (emphasis added).

"These examination guidelines indicate that the Office views the 'or otherwise available to the public' residual clause of the AIA's 35 U.S.C. 102(a)(1) as indicating that secret sale or use activity does not qualify as prior art ... [and] that an activity (such as a sale, offer for sale, or other commercial activity) is secret (non-public) if, for example, it is among individuals having an obligation of confidentiality to the inventor." *Id.* at 11060. The PTO explained that "[r]esidual clauses such as 'or otherwise' or 'or other' are generally viewed as modifying the preceding phrase or phrases," and that "[t]herefore, the Office views the 'or otherwise available to the public' residual clause of the AIA's 35 U.S.C. 102(a)(1) as indicating that secret sale or use activity does not qualify as prior art." *Id.* at 11062 (citations omitted). It also noted "that the Office's interpretation is consistent with the interpretation that was clearly expressed by the bicameral sponsors of the AIA during the congressional deliberations on the measure." *Id.* (citations omitted).

The PTO also observed that some commentators said that "interpreting the 'on sale' provision to require public availability is good public policy in that it would lower litigation costs by simplifying discovery, and would reduce unexpected prior art pitfalls for inventors who are not well versed in the law." *Id.*

The PTO's interpretation not only is the most natural reading of the statute, but also reflects close attention to the statute's legislative history.

### F. The Federal Circuit's Opinion Is Inconsistent with Established Canons of Statutory Construction.

#### 1. Noscitur a Sociis: The "On Sale" Bar Reflects the "Company It Keeps."

Even if § 102 were ambiguous (which it is not), the "on sale" bar should be construed as requiring that an invalidating sale must be public. When a word or term of a statute is ambiguous or its meaning is doubtful, it may be interpreted in light of its associates, just like one "may know a person by the company he keeps." *Brown v. Chicago & N. W. R. Co.*, 77 N.W. 748, 752 (Wis. 1899).

The rule of noscitur a sociis (or the associated-words canon) "is a rule of construction to be applied where there is doubt and ambiguity concerning the meaning of a word or expression used by the legislative body in enacting a statute." *X-Acto Crescent Prods. Co., Inc. v. United States*, 27 Cust. Ct. 190, 192 (U.S. 1951); *see also Jarecki v. G. D. Searle & Co.*, 367 U.S. 303, 307 (1961) ("The maxim *noscitur a sociis*, that a word is known by the company

it keeps, while not an inescapable rule, is often wisely applied where a word is capable of many meanings in order to avoid the giving of unintended breadth to the Acts of Congress."); *Gustafson v. Alloyd Co.*, 513 U.S. 561, 575 (1995); *Gutierrez v. Ada*, 528 U.S. 250, 255 (2000); *Yates v. United States*, 135 S. Ct. 1074, 1085 (2015).

For example, a statute saying "signed, or otherwise adopted or approved," was interpreted "by ordinary principles of noscitur a sociis" as meaning "an approval comparable to a signature." *United States v. Begaye*, 236 F.R.D. 448, 451 (D. Ariz. 2006) (discussing *Campbell v. United States*, 296 F.2d 527, 532-33 (1st Cir. 1961)). In *Jarecki*, this Court applied the maxim noscitur a sociis and said that in a statute having three words in conjunction—"exploration, discovery, or prospecting"—the word "discovery" "gathers meaning from the words around it," and because these words describe activity in the oil and gas and mining industries, "discovery" cannot be applied to development and manufacture of drugs and cameras. 367 U.S. at 307.

In accordance with the noscitur a sociis canon, the term "on sale" should be interpreted by association with both its closest neighbors ("in public use" and "otherwise available to the public") and its more distant neighbors ("patented" and "described in a printed publication"), all of which denote public availability.[11]

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11. Another related canon, the ejusdem generis rule (according to which, in a series of words of description, a general word can be limited to a meaning similar to that of objects of a like kind with the specified terms), further supports commonality of interpretation here. The U.S. Courts of Customs and Patent Appeals applied the ejusdem generis canon to hold that the

### 2. The "Last Antecedent" Canon Is Inapplicable.

The "last antecedent" doctrine, referenced in the concurring opinion in the Federal Circuit's order denying en banc review, *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.*, No. 2016-1284, 2016-1787, slip op. at 7 (Fed. Cir. Jan. 16, 2018) ("Slip op."), is inapplicable here. The last antecedent rule "provides that 'a limiting clause or phrase . . . should ordinarily be read as modifying only the noun or phrase that it immediately follows'" and "reflects the basic intuition that when a modifier appears at the end of a list, it is easier to apply that modifier only to the item directly before it." *Lockhart v. United States*, 136 S. Ct. 958, 962-63 (2016) (quoting *Barnhart v. Thomas*, 540 U.S. 20, 46 (2003)).

The concurring opinion suggests that "the doctrine implies that 'to the public' limits only 'otherwise available.'" Slip op. at 7. Here, however, "otherwise" modifies "available to the public," not the other way around. Moreover, the "noun or phrase" immediately before "or otherwise available to the public" is "on sale."

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term "otherwise manufactured" in a provision stating that "[p]earl, mother of, and shells, not sawed, cut, flaked, polished, or otherwise manufactured" was to "take color and meaning from the enumerated operations, which are to be regarded as manufacturing operations within the purview" of this paragraph. *August Bentkamp v. United States*, 40 C.C.P.A. 70, 73, 77 (C.C.P.A. 1952). "To hold differently would be to ignore the plain meaning of the ... statutory language and *would in effect eliminate and render meaningless the word "otherwise"* in each of the[] paragraphs [at issue]. This is a result which we believe Congress clearly could not have intended." *Id.* at 77 (emphasis added).

If anything, application of the "last antecedent rule" would result in "otherwise available to the public" applying to "on sale."

The structure of § 102(a) does not invite application of the "last antecedent rule," because the type of "limiting clause or phrase" that calls for application of this doctrine is not present in the statute. Application of the canon also results in a cramped reading that is true neither to the provision's actual language nor to its legislative history. *Davis* v. *Michigan Dep't of Treasury*, 489 U.S. 803, 809 (1989) ("It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme").

The "last antecedent rule" simply is not a good linguistic fit here.

### G. This Case Is an Ideal Vehicle for Addressing the Issue of Whether a Sale to a Third Party Subject to an Obligation to Keep the Invention Confidential Qualifies as Prior Art Under the AIA "On Sale Bar."

The scope of invalidating prior art is of critical importance in our patent system. The Court's intervention is required, at this time, to provide a definitive answer to the question at hand, so as to restore a measure of predictability and certainty in the U.S. patent system, and avoid countless unnecessary decisions and litigation interpreting and applying a wrong rule of law.

All participants in the patent system—inventors trying to develop their inventions and seeking partners to do so, companies deciding to enforce their own patents or to license or acquire patents from others, and investors valuing the patent portfolios of potential investment targets—must be able to determine what constitutes potentially invalidating prior art under the AIA, and what does not. The line between the two informs participants' decisions about how best to invest their resources, and whether or not to invest in innovation. Those decisions are based not only on their understanding of the law but also on their reliance on its stability. Uncertainty about the scope of invalidating prior art—and therefore about the scope of patent rights—benefits no one. It only decreases the patent system's ability to fulfill its purpose of fostering innovation and fueling economic growth.

This case presents an ideal vehicle for addressing the question of whether § 102(a) encompasses agreements where a third party is obligated to keep the invention confidential, because there are no factual disputes that could cloud the legal inquiry; the parties in this case do not dispute that the allegedly invalidating transactions at issue did not make the claimed invention itself publicly available. The question of whether such transactions constitute invalidating sales under the AIA is crucial for this Court to resolve at this time.

The Federal Circuit's *Helsinn* opinion indicates that its finding that the "on sale" bar applied was limited to the "particular Supply and Purchase Agreement" before it, but that finding necessarily turned on its conclusion that "if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms

of sale" in order for the "on sale" bar to apply. *Helsinn*, 855 F.3d at 1371. This broad construction of the "on sale" bar is directly contrary to the plain meaning of 35 U.S.C. § 102(a)(1), contrary to its purpose, contrary to its legislative history, and would defeat the efforts of the House and the Senate to harmonize the U.S. view of what counts as prior art with the views of the rest of the world. The "devil is in the details"—"prior art" cannot be invalidating prior art unless it makes the claimed invention available to the public. The Federal Circuit's characterization, its conclusion was not limited to the "particular Supply and Purchase Agreement" before it; rather, the court's conclusion necessarily turned on its holding that "if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of sale" in order for the "on sale" bar to apply. *Helsinn*, 855 F.3d at 1371. This approach is directly contrary to the plain meaning of 35 U.S.C. § 102(a)(1), contrary to its purpose, contrary to its legislative history, and would defeat the efforts of the House and the Senate to harmonize the U.S. view of what counts as prior art with the views of the rest of the world. The "devil is in the details"—"prior art" cannot be invalidating prior art unless it makes the claimed invention available to the public.

## V. Conclusion

For the foregoing reasons, US Inventor respectfully requests that the Court grant Helsinn's petition for a writ of certiorari.

Respectfully submitted,

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